IN THE CIVIL DISTRICT COURT
OF THE PARISH OF ORLEANS

FILED
2018 FEB -6 P 3:52
CIVIL
DISTRICT CT.

ADDICTION RECOVERY RESOURCES, INC., a LOUISIANA CORPORATION,

Plaintiff,

VS. CASE NO.: 2018-01197
L-6

MORRIS & DICKSON CO., LLC;
MCKESSON CORPORATION;
CARDINAL HEALTH, INC.;
AMERISOURCEBERGEN CORPORATION;
CVS HEALTH CORPORATION;
WALGREENS BOOTS ALLIANCE, INC.;
WAL-MART STORES, INC.;
PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
ALLERGAN PLC f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS LLC;
ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.,
MALLINCKRODT, PLC d/b/a MALLINCKRODT PHARMACEUTICALS,

Defendants.

PETITION FOR DAMAGES

Comes now the Plaintiff, ADDICTION RECOVERY RESOURCES, INC., a Louisiana corporation (hereinafter referred to as "ARR"), by and through its attorneys, and files suit against the Defendants and would show as follows:

INTRODUCTION

1. The addiction epidemic of prescription opioid abuse in the United States has caused health care providers, including ARR, extraordinary economic damages, substantial loss of resources, employee disability, and myriad human and capital costs. This epidemic is the largest health care crisis in U.S. history, and it has financially harmed ARR to the point that it has hampered its ability to provide health and addiction services throughout

Louisiana.

2. Prescription opioids are deadlier than heroin. According to the National Institutes of Health, prescription opioids kill almost twice as many people in the United States as heroin. Prescription opioids and related drug overdose deaths surpass car accident deaths in the U.S. The costs to health care are overwhelming.

3. This epidemic and its consequences could have been, and should have been, prevented by the Defendants who control the U.S. drug distribution industry and the Defendants who manufacture the prescription opioids. These Defendants have profited greatly by allowing the geographic area that ARR serves to become flooded with prescription opioids.

4. The drug distribution industry is supposed to serve as a "check" in the drug delivery system, by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. Defendants woefully failed in this duty, instead consciously ignoring known or knowable problems and data in their supply chains.

5. Defendants thus intentionally and negligently created conditions in which vast amounts of opioids have flowed freely from drug manufacturers to innocent patients who became addicted, to opioid abusers, and even to illicit drug dealers - with distributors regularly fulfilling suspicious orders from pharmacies and clinics, who were economically incentivized to ignore "red flags" at the point of sale and before dispensing the pills.

6. Defendants' wrongful conduct has allowed millions of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in the patient demographic area of ARR. This is characterized as "opioid diversion." Acting against their common law and statutory duties, Defendants have created an environment in which opioid diversion is rampant. As a result, unknowing patients and unauthorized opioid users have ready access to illicit sources of diverted opioids.

7. For years, Defendants and their agents have had the ability to substantially reduce the death toll and adverse economic consequences of opioid diversion, including the deaths and health ruination of hundreds of thousands of citizens. Substantial expenditures by ARR in dealing with the problem have gone un-recouped and unreimbursed. All the Defendants in this action share responsibility for perpetuating the epidemic.

8. Defendants have foreseeably caused damages to ARR including the unreimbursed

and/or un-recouped costs of providing: (a) opioid addiction treatment; (b) counseling and rehabilitation services; (c) security and public safety; (c) lost opportunity costs; (d) the diversion of assets from the provision of other needed health treatments; and (e) increased human resources costs as well as lost productivity of its employees. Insurance companies typically cover patient costs associated with addiction treatment for only a small window of time. That timeframe, however, is insufficient for effective opioid addiction treatment. Consequently, ARR has incurred costs, at its own expense, to provide adequate addiction treatment to its opioid-addicted patients.

9. ARR brings this Petition for Damages for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors, retailers, and manufacturers that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably injured, and continues to injure, ARR.

PARTIES

10. The Plaintiff ARR is Louisiana corporation with its principal place of business in Louisiana. ARR specializes in treating patients who suffer from alcohol and drug addiction through a portfolio of services including, but not limited to, ambulatory detoxification, residential treatment programs, intensive outpatient treatment programs, and transitional living programs. The opioid epidemic has flooded ARR with patients who require ARR's services. These services often times go unpaid and has consequently resulted in a massive accumulation of unreimbursed costs.

11. Morris and Dickson Co., LLC ("Morris and Dickson") is Louisiana limited liability company and maintains its principal place of business in Shreveport, Louisiana. Upon information and belief, during all relevant times, Morris and Dickson distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of patients and employees of ARR.

11. McKesson Corporation ("McKesson") has its principal place of business in San Francisco, California and is incorporated under the laws of Delaware. During all relevant times, McKesson has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of patients and employees of ARR.

12. Cardinal Health, Inc. ("Cardinal") has its principal place of business in Ohio and is incorporated under the laws of Ohio. During all relevant times, Cardinal has distributed substantial

amounts of prescription opioids to providers and retailers in the geographic area of patients and employees of ARR.

13. AmerisourceBergen Corporation has its principal place of business in Pennsylvania and is incorporated under the laws of Delaware. During all relevant times, AmerisourceBergen has distributed substantial amounts of prescription opioids to providers and retailers in the geographic area of patients and employees of ARR.

14. Morris and Dickson, McKesson, Cardinal, and AmerisourceBergen are collectively referred to hereinafter as "Distributor Defendants."

15. CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island. During all relevant times, CVS Health has sold and continues to sell prescription opioids in close proximity to ARR.

16. Walgreens Boots Alliance, Inc., a/k/a Walgreen Co. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Walgreens has sold and continues to sell prescription opioids in close proximity to ARR.

17. Wal-Mart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Arkansas. At all relevant times, Wal-Mart has sold and continues to sell prescription opioids at locations in close proximity to ARR..

18. CVS Health, Walgreens, and Wal-Mart are collectively referred to hereinafter as the "Pharmacy Defendants."

19. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and Louisiana. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

20. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Louisiana. Actiq and Fentora have been approved by the

FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

21. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly- owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

22. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the U.S. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S. through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Louisiana, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Louisiana, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own. Through interrelated operations like these, Teva Ltd. operates in Louisiana and the rest of the U.S. through its subsidiaries Cephalon and Teva USA. The U.S. is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as "Cephalon.")

23. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New

Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J hereinafter are collectively referred to as "Janssen."). Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Louisiana, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

24. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly- owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. hereinafter are collectively referred to as "Endo.") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Louisiana. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Louisiana, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

25. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, later to Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc. f/k/a Watson

Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over and derives financial benefit from the marketing, sales, and profits of Allergan/Actavis products. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are referred to collectively as "Actavis.") Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Louisiana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

26. Mallinckrodt, PLC, an alien company doing business as Mallinckrodt Pharmaceuticals with its principal place of business in the United States in St. Louis, Missouri, is one of the largest manufacturers of the generic opioid oxycodone.

27. Purdue, Cephalon, Janssen, Endo, Actavis, and Mallinckrodt are collectively referred to hereinafter as the "Pharmaceutical Defendants."

28. The Plaintiff presently lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. The Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained. The Plaintiff is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

JURISDICTION AND VENUE

29. This Court has subject matter jurisdiction of this case because the amount in controversy exceeds the jurisdictional minimum.

30. Defendants have engaged in conduct and activities over a long time, systematically, individually, jointly, and severally, in Louisiana and the geographic area served by ARR that have caused all of the Plaintiff's damages and all of which form the bases of the causes of action in this

Complaint as against Defendants. Defendants have committed multiple torts and breaches within the geographic areas ARR serves, repeatedly and systematically.

31. Defendants have systematic and substantial contacts and business relationships within the geographic areas served by ARR.

32. This Court has personal jurisdiction over Morris and Dickson because Morris and Dickson is headquartered in Louisiana. This Court has personal jurisdiction over the remaining Defendants because each Defendant has committed the alleged torts herein, in part or in whole, within the State of Louisiana and the geographic area served by ARR, as alleged herein. All causes of action herein relate to Defendants' wrongful actions, conduct, and omissions committed against ARR, and the consequences and damages related to said wrongful actions, conduct, and omissions.

33. Venue is proper in this Court in that a substantial part of the events giving rise to the claims occurred in this District.

BACKGROUND FACTS

34. Opioid means "opium - like" and the term includes all drugs derived in whole or in part from the opium poppy.

35. The United States Food and Drug Administration's website describes this class of drugs as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death."

36. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the Controlled Substances Act. They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

37. Before the epidemic of Defendants' prescription opioids, the generally accepted standard of medical practice was that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the

serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

PHARMACEUTICAL DEFENDANTS' WRONGFUL CONDUCT

38. To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and deceptive marketing and/or distribution scheme targeted at consumers and physicians. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence. These statements were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations, including those in the geographic area served by ARR.

39. The Pharmaceutical Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Louisiana. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of ARR.

40. The Pharmaceutical Defendants' direct and branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue ran a series of ads, called "Pain Vignettes," for OxyContin that featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. While Endo and Purdue agreed in 2015-16 to stop these particularly misleading representations in New York, they continued to disseminate them in Louisiana.

41. The Pharmaceutical Defendants also promoted the use of opioids for chronic pain through "detailers" – sophisticated and specially trained sales representatives who visited

individual doctors and medical staff, and fomented small-group speaker programs. In 2014, for instance, these Defendants spent almost $200 million on detailing branded opioids to doctors.

42. The FDA has cited at least one of these Defendants for deceptive promotions by its detailers and direct-to-physician marketing. In 2010 an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

43. The Pharmaceutical Defendants invited doctors to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by these Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

44. The Pharmaceutical Defendants' detailing to doctors was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.

45. The Pharmaceutical Defendants have had unified marketing plans and strategies from state to state, including Louisiana. This unified approach ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.

46. The Pharmaceutical Defendants deceptively marketed opioids in Louisiana through unbranded advertising that promoted opioid use generally, yet silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents.

47. The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the deceptive messages came from an independent and objective source.

48. The Pharmaceutical Defendants' deceptive unbranded marketing also contradicted their branded materials reviewed by the FDA.

49. The Pharmaceutical Defendants marketed opioids through a small circle of doctors who were vetted, selected, funded, and promoted by these Defendants because their public positions supported the use of prescription opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs." These Defendants paid KOLs to serve in a number of doctor-facing and public-facing capacities, all designed to promote a pro-opioid message and to promote the opioid industry pipeline, from manufacture to distribution to retail.

50. These Defendants entered into and/or benefitted from arrangements with seemingly unbiased and independent organizations or groups that generated treatment guidelines, unbranded materials, and programs promoting chronic opioid therapy, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

51. The Pharmaceutical Defendants collaborated, through the aforementioned organizations and groups, to spread deceptive messages about the risks and benefits of long-term opioid therapy.

52. To convince doctors and patients in Louisiana that opioids can and should be used to treat chronic pain, these Defendants had to persuade them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.

53. To convince doctors and patients that opioids are safe, the Pharmaceutical Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (a) starting

patients on opioids was low- risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

54. The Pharmaceutical Defendants falsely claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these false and deceptive claims by opioid manufacturers are: (a) Actavis employed a patient education brochure that falsely claimed opioid addiction is "less likely if you have never had an addiction problem"; (b) Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain*, falsely claiming that addiction is rare and limited to extreme cases of unauthorized doses; (c) Endo sponsored a website, Painknowledge.com, which falsely claimed that "[p]eople who take opioids as prescribed usually do not become addicted"; (d) Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "most people do not develop an addiction problem"; (e) Janssen distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* which described as "myth" the claim that opioids are addictive; (f) a Janssen website falsely claimed that concerns about opioid addiction are "overestimated"; and (g) Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – that falsely claims that pain is undertreated due to "misconceptions about opioid addiction."

55. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder."

56. The FDA further exposed the falsity of the Pharmaceutical Defendants' claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013

and for other opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

57. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. This agreement, however, did not extend to Louisiana.

58. The Pharmaceutical Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudo-addiction" – a term used by Dr. David Haddox, who went to work for Purdue, and Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue. Defendants falsely claimed that pseudo-addiction was substantiated by scientific evidence. Some examples of these deceptive claims are: (a) Cephalon and Purdue sponsored *Responsible Opioid Prescribing*, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudo-addiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated"; (c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudo-addiction by teaching that a patient's

aberrant behavior was the result of untreated pain; (d) Purdue sponsored a deceptive CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse* in which a narrator notes that because of pseudo-addiction, a doctor should not assume the patient is addicted.

59. The 2016 CDC Guideline rejects the concept of pseudo-addiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer- term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

60. The Pharmaceutical Defendants falsely instructed doctors and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Pharmaceutical Defendants directed them to general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Pharmaceutical Defendants' misrepresentations were intended to make doctors more comfortable in prescribing opioids. Some examples of these deceptive claims are: (a) an Endo supplement in the *Journal of Family Practice* emphasized the effectiveness of screening tools to avoid addictions; (b) Purdue's webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths"; (c) Purdue represented in scientific conferences that "bad apple" patients – and not opioids – were the source of the addiction crisis, when in fact the "bad apples" were the Defendants.

61. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." The Guideline emphasizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

62. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Pharmaceutical Defendants falsely claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

63. A CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, that claimed "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," without mentioning any known or foreseeable issues.

64. Pharmaceutical Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. The 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

65. The Pharmaceutical Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences, and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example: (a)

an Actavis patient brochure stated - "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction"; (b) Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain*, claiming that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain; (c) an Endo website, painknowledge.com, claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain"; (d) an Endo pamphlet *Understanding Your Pain: Taking Oral Opioid Analgesics*, stated "The dose can be increased. . . . You won't 'run out' of pain relief"; (e) a Janssen patient education guide *Finding Relief: Pain Management for Older Adults* listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages; (f) Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will; (g) Purdue's *A Policymaker's Guide to Understanding Pain & Its Management* stated that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages; (h) a Purdue CME entitled *Overview of Management Options* taught that NSAIDs and other drugs, but not opioids, were unsafe at high dosages; (i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

66. These and other representations conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

67. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."